K111138

JUN 22 2011

510(K) SUMMARY

11.1 SUBMITTER INFORMATION

A.	Company Name:	Access Scientific, Inc.
B.	Company Address:	12526 High Bluff Drive, Suite 360 San Diego, CA 92130
C.	Company Phone:	(858) 259-8333
D.	Company Facsimile:	(858) 259-5298
E.	Contact Person:	Albert Misajon Vice President, Regulatory Affairs and Quality Assurance amisajon@the-wand.com
F.	Date Summary Prepared:	June 3, 2011

11.2 DEVICE IDENTIFICATION

A.	Device Trade Name:	the PICC WAND® Peelable Safety Introducer
B.	Common Name:	Catheter Introducer
C.	Classification Name(s):	Introducer, Catheter
D.	Classification Regulation(s):	21 CFR 870.1340
E.	Device Class:	Class II
F.	Product Code:	DYB
G.	Advisory Panel:	Cardiovascular

11.3 IDENTIFICATION OF PREDICATE DEVICE

The predicate device is the PICC WAND® Peelable Safety Introducer that was cleared for commercial distribution under 510(k) K101150.

11.4 DEVICE DESCRIPTION

The PICC WAND® Peelable Safety Introducer is an all-in-one preassembled intravascular catheter introducer that consists of the following basic introducer components: Introducer Needle, Nitinol Guidewire, Dilator and a peelable Sheath Introducer. It is intended to provide the clinician with a safe, simple and accelerated approach, using the Accelerated Seldinger Technique, to place an in-dwelling intravascular catheter through the skin into the circulatory system. The peelable Sheath Introducer allows for the placement of peripherally inserted central catheters (PICC) and midline catheters. The device includes a Fast-flash™ feature that provides the clinician with feedback that the introducer needle is in the

intraluminal position within the blood vessel. The device also incorporates a safety mechanism to guard against accidental needle stick.

11.5 INDICATIONS FOR USE

The PICC WAND® Peelable Safety Introducer is used to facilitate the placing of an intravascular catheter through the skin into the circulatory system.

11.6 TECHNOLOGICAL CHARACTERISTICS

The proposed modified device has the same technological characteristics as the predicate device in terms of components, materials, chemical composition, and design. The changes to the device are in the mechanism of attaching/detaching the Needle Hub to the Dilator Hub. Performance testing has been conducted to confirm that the modified device satisfies performance requirements.

In addition to the changes identified above, the following changes have been implemented via letter-to-file since the clearance of the 510(k) for the predicate PICC WAND Peelable Safety Introducer:

1. Dimensional changes to Components:
   - Length of Guidewire reduced from 9.45" to 9.045" (Δ=0.405")
   - Length of Dilator reduced from 5.056" to 4.383" (Δ=0.673")
   - Length of Sheath Introducer reduced from 4.054" to 3.380" (Δ=0.674")
   - Fast-flash hole in Needle sidewall moved from 4.487" distal to hub to 3.380" distal to hub (Δ=0.835")
2. Changed packaging from Tyvek® pouch to thermoformed tray with Tyvek® lid
3. Added 4Fr. & 6Fr. sizes
4. Removed numbers from the Dilator Hub, Dilator Nut, and Guidewire Cap
5. Modified Labels and DFU for clarity to insure easier, safer, and more effective use

Performance testing has been conducted, as necessary, to confirm that the modified device satisfied performance requirements.

11.7 SUMMARY OF TESTING

Design verification testing was conducted to demonstrate that the performance characteristics of the modified PICC WAND® Peelable Safety Introducer are equivalent to the predicate device and satisfy the requirements of the product design specification for its intended use.

This testing included the following:

Special 510(k) Modification:

1. Needle Hub and Dilator Hub Attachment

Testing to qualify Special 510(k) modification

1. Needle Hub to Dilator Separation Force and Removal Force
2. Axial force Testing

Letter-to-file Modifications (i.e. changes that have been implemented via letter-to-file since the clearance of the 510(k) for the predicate PICC WAND Peelable Safety Introducer):

1. Dimensional changes to components
2. Change to packaging from Pouch to Tray
3. Added 4 Fr. & 6 Fr. sizes

Testing to qualify letter-to-file modifications:

1. Dimensional changes to components
    - Axial force tests
    - Insertability tests
    - Fast Flash evaluation
2. Change packaging from Pouch to Tray
    - Packaging
        i. Seal testing
        ii. Sterile Barrier/Bubble leak testing
        iii. Shipping and shelf life testing
    - Sterilization cycle adoption study
3. Added 4 Fr. and 6 Fr. sizes
    - Dilator – Distal/tip columnar strength
    - Dilator – Tensile Strength of Union(Tube to Hub)
    - Sheath Introducer – Distal/tip columnar strength
    - Sheath Introducer – Tensile Strength of Union(Tube to Hub)
    - System insertability
    - System – Intraluminal visual indicators
    - System – Fast-flash function and timing
    - Shelf life (accelerated aging) to labeled expiration date

11.8 CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the modified PICC WAND® Peelable Safety Introducer is substantially equivalent to the predicate device in design, function, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Access Scientific, Inc.
C/O Albert Misajon
12526 High Bluff Drive, Suite 360
San Diego, CA 92130

JUN 2 2 2011

Re: K111138
Trade/Device Name: The PICC WAND® Peelable Safety Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: June 3, 2011
Received: June 6, 2011

Dear Mr. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: the PICC WAND® Peelable Safety Introducer

Indications for Use:

The PICC WAND® Peelable Safety Introducer is used to facilitate the placing of an intravascular catheter through the skin into the circulatory system.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111138